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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,184	12/19/2001	Chad Cori Huval	1932.1064-033	8481
21005	7590	08/10/2007	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.			WILLIAMS, LEONARD M	
530 VIRGINIA ROAD			ART UNIT	
P.O. BOX 9133			PAPER NUMBER	
CONCORD, MA 01742-9133			1617	
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			08/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/025,184

Applicant(s)

HUVAL ET AL.

Examiner

Leonard M. Williams

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 8-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Detailed Action

Examiner's Note

The examiner notes that the preliminary matter presented on page 4 of the applicant's remarks was an inadvertant statement based on the previous office action and applicant correctly surmised that it did not pertain to the claims and remarks presented at that time.

Response to Amendment

Applicant's amendment received 03/22/2007 amending claim 2 and adding new claims 11-13 is entered.

Claims 2-3 and 8-13 are pending.

Applicant's arguments with respect to claims 2-3 and 8-10 have been considered but are moot in view of the new rejection necessitated by applicant's amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-3 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keim et al. (US Patent No. 3700623) in view of McTaggart et al. (US Patent No. 5462730).

Keim et al. teach, in col. 1 lines 20-55, water-soluble resinous reaction products of a polymer of a diallylamine and an epihalohydrin such as epichlorohydrin. The resins are fast curing, water-soluble, and efficient. In example 5, 5g of diallyl amine monomer is reacted with 1g of epichlorohydrin cross-linking agent giving a 20% by weight amount of cross-linking agent. In example 6 the polymer to cross-linking agent percentage is 15.9%. In column 2 lines 63-70, Keim et al. teaches that the polymers can be homopolymers or copolymers and can exist as the salts or freebase of the final amines. Keim et al. teach, in col. 3 lines 50-70, that the resinous products are soluble in water and the pH of the solutions can be adjusted to 6 or 5 by addition of hydrochloric, sulfuric, phosphoric, and acetic acids.

Keim et al. does not explicitly teach the resin to be used in pharmaceutical compositions.

McTaggart et al. teaches, in col. 1 line 10- col. 2 line 40, poly(allylamine)polymeric materials (that can be cross-linked) useful in the formulation of pharmaceutical agents for sequestering bile acid and thus having utility in treating a variety of disorders including hypercholesterolemia, etc... In col. 9 line 5 to col. 10 line 28, McTaggart et al. teach that the polymeric allylammonium compositions can be formulated in suspensions and as tablets for oral administration.

One of ordinary skill in the art at the time the invention was made would recognize that Keim et al.'s homopolymer (capable of being neutralized by pharmaceutically acceptable acids) could be formulated into pharmaceutically forms (such as tablets) for oral administration as McTaggart demonstrates that similar

polyallylamine polymers can be formulated as such. Further McTaggart et al. Demonstrate that polyallylamine polymers of this type have utility as bile sequestering agents. As the homopolymers Keim et al. detail are exactly the polymers currently claimed, the properties the applicant's have discovered are inherently present in Keim et al.'s. homopolymers. Thus the homopolymers currently claimed were known and similar polymers have already been formulated into pharmaceutical forms for use as bile acid sequestrants.

"Products of identical chemical composition can not have mutually exclusive properties. " A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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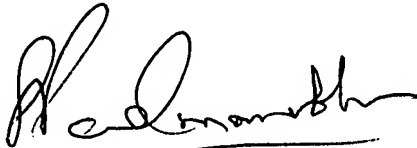
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER